IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13
11/2/99

In re application of

John Carney et al

Serial No. 08/962,040

Filed: October 31, 1997

Examiner D. Jones

Art Unit 1614

For: SPIN-TRAPPING PHARMACEUTICAL COMPOSITIONS AND METHODS OF USE THEREOF

REQUEST FOR RECONSIDERATION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the Official Action of April 28, 1999, favorable reconsideration and allowance of all pending claims respectfully is requested. For the reasons indicated in detail below, these claims are believed to define patentable subject matter.

By way of review, the claimed invention is directed to a method for the prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration. Claims directed to the composition used to accomplish this method have been withdrawn from consideration as

a result of a restriction requirement.

Applicants thank the Examiner for the courtesy extended toward their representative Mr. James W. Hellwege during the interview of July 21, 1999. During the interview, those distinctions that exist between the claimed invention and the cited prior art were discussed. The substance of the interview is discussed at greater detail below.

Claims 28-51 stand rejected under 35 USC 103 over Cox et al British Patent 1,109,473, Dorschner et al U.S. Patent No. 3,834,073 and Schlesinger U.S. Patent No. 3,775,122. These rejections are respectfully traversed.

In response, it is noted that none of the cited references are directed to pharmaceutical compositions or to a a method for the prophylaxis or treatment of a patient as claimed. Instead, the Cox reference is directed to light-sensitive diazotype materials which contain UV-absorbing compounds. Dorschner et al is directed to the use of phenyl nitrone derivatives as seed protectants. The Schlesinger patent is directed to the use of photosensitive nitrones in an image-formation system. No mention is made in the references (nor does any suggestion exist) as to the use of the claimed compounds in a topical pharmaceutical preparation as claimed by applicants. The rejections under 35 USC 103 are accordingly improper and should be withdrawn.

Claims 28-51 stand further rejected as being unpatentable over prior U.S. Patent No. 5,025,032 on the grounds of obviousness-type double patenting. This rejection is also respectfully traversed.

In response, U.S. Patent No. 5,025,032 (now Reissue Patent No. 35,112) claims a

method for in vivo treatment of oxidative CNS tissue damage. As discussed during the interview, the use of phenyl butyl nitrone compounds in vivo to treat CNS tissue damage is a clearly distinct method from that claimed by applicants; i.e., a method for the "prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration". No obviousness-type double patenting thus exists, and the rejection should accordingly be withdrawn.

Claims 28, 36, 37, 39, 40, 43, 45, 50 and 51 stand rejected under 35 USC 112 (first paragraph) on the ground that the specification is not sufficiently enabling for the use of the term "spin trapping compound". This rejection is respectfully traversed.

The initial burden of establishing a prima facie case of non-enablement rests with the Examiner. In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971); In re Strahilevitz, 212 USPQ 561, 563 (CCPA 1982).

"Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasons substantiating the doubts so expressed." In re Dinh-Nguyen and Stenhagen, 181 USPQ 46, 47 (CCPA 1974). See also In re Bowen, 181 USPQ 48 (CCPA 1974); In re Gardner, 177 USPQ 396, 397 (CCPA 1973).

It is only required that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that the applicant invented the subject matter

that is now claimed in order to comply with the requirements of the statute. In re Smyth, 178 USPQ 279, 284 (CCPA 1973).

The statute merely requires that the scope of the claims bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill. In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

An enabling disclosure under 35 USC 112 is one which allows those skilled in the art to make and use the claimed invention without undue experimentation. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 94 (Fed. Cir. 1986).

Notwithstanding the Examiner's failure to meet his burden under 35 USC 112, the Examiner takes the position (without factual basis) that the claimed invention lacks enabling support in the specification. The Examiner apparently believes that the claims should be limited to the compounds particularly identified in the specification. However, to restrict the pending claims solely to the exemplified compounds would be improper, unduly restrict the claimed invention, and be without legal basis.

The Examiner has not provided any evidence or scientific reasoning why one skilled in the art could not practice the claimed invention. Indeed, the Examiner cannot provide such evidence because this is simply not true. The rejection is accordingly improper and should be withdrawn.

Claims 28 and 30 stand further rejected under 35 USC 112 (paragraph one) on the ground that the specification is not enabling for the treatment of a patient suffering from a

dysfunction or disease condition arising from "oxidative damage" as opposed to oxidative damage resulting from ultraviolet radiation. This rejection is respectfully traversed.

Applicants have exemplified a wide variety of dysfunctions or disease conditions arising from "oxidative damage" at page 20 of the instant specification. One skilled in the art can accordingly readily practice with some predictability the claimed invention as applicable "oxidative damage" disease conditions are well described. The rejection should accordingly be withdrawn.

As also discussed during the interview, applicants have previously filed a request for the institution of an interference between the pending claims and the claims of U.S. Patent No. 5,679,691 (Ribier et al). The '691 patent is directed to a topical spin trap composition for the light protective, anti-aging and/or anti-acne treatment of the skin. See applicants' Request for Interference filed September 18, 1998 in the instant application. Applicants have previously proposed the following count:

> Count: A method for the prophylaxis or treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration to said patient.

At least claims 1, 2, 3, 4, 5, 12 and 13 of the patent correspond to the proposed count. Claims 28-51 of the instant application also correspond to the proposed count. See, also, applicants' Request for Interference in which an earliest effective date for the

claimed invention of June 18, 1991 is demonstrated, which antedates the effective date of the '691 patent. As applicants' effective filing date is prior to the effective filing date of the '691 patent, no showing pursuant to 37 CFR 1.608 is required. Also, applicants' pending claims were presented within one year of the issue date of the '691 patent in accordance with 35 USC 135.

An interference is appropriate between an application and an unexpired patent of different parties when the application and the patent contain claims to the same patentable invention. 37 CFR 1.601(i) and 1.601(n). Claims 28-51 of the instant invention and claims 1, 2, 3, 4, 5, 12 and 13 of the '691 patent are directed to the same patentable invention. Indeed, notwithstanding the rejections under 35 USC 112 (paragraph one), at least claims 42, 46, 47, 48 and 49 of the instant application are directed to allowable subject matter and form the basis for an interference.

In view of the above, it is believed that all pending claims are directed to allowable subject matter. Further, applicants have presented sufficient basis for the institution of an interference between the instant application and U.S. Patent No. 5,679,691, and an interference should accordingly be instituted at an early date.

Respectfully submitted,

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